

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT



(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>P55434PC00</b>	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. <b>PCT/NL02/00314</b>	International filing date (day/month/year) <b>16/05/2002</b>	Priority date (day/month/year) <b>21/05/2001</b>
International Patent Classification (IPC) or national classification and IPC <b>C12N15/86</b>		
Applicant <b>ID-LELYSTAD, INSTITUUT VOOR DIERHOUDERIJ..et al.</b>		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.  
  
☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  
  
 These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand  <b>16/12/2002</b>	Date of completion of this report  <b>26.08.2003</b>
Name and mailing address of the international preliminary examining authority:   <b>European Patent Office</b> <b>D-80298 Munich</b> <b>Tel. +49 89 2399 - 0 Tx: 523656 epmu d</b> <b>Fax: +49 89 2399 - 4465</b>	Authorized officer  <b>Petri, B</b>  <b>Telephone No. +49 89 2399 7356</b> 

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/NL02/00314

## I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):  
**Description, pages:**

1-47 as originally filed

### Claims, No.:

1-15 as originally filed

### Drawings, sheets:

1/13-13/13 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/NL02/00314

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Yes:	Claims
	No:	Claims 1-15
Inventive step (IS)	Yes:	Claims
	No:	Claims 1-15
Industrial applicability (IA)	Yes:	Claims 1-15
	No:	Claims

2. Citations and explanations  
**see separate sheet**

The present application relates to deletion mapping of genomic sequences within structural proteins to determine parts which are essential for viral replication and /or transcription and in particular to the identification of essential cis-acting elements essential for viral replication within ORF7 of porcine arterivirus.

D1: MOLENKAMP RICHARD ET AL: 'The arterivirus replicase is the only viral protein required for genome replication and subgenomic mRNA transcription.' JOURNAL OF GENERAL VIROLOGY, vol. 81, no. 10, October 2000 (2000-10), pages 2491-2496, XP002176270 ISSN: 0022-1317

Is directed to the identification of essential genes within arterivirus. Discloses arterivirus replicons having at least some of the ORF7 deleted (Fig 2).

D2: BRAMEL-VERHEIJE ET AL.: 'Identification of an essential viral reproduction signal in ORF7 of porcine reproductive and respiratory syndrome virus.' THE VIII INTERNATIONAL SYMPOSIUM ON NIDOVIRUSES (CORONAVIRUSES AND ARTERIVIRUSES), 20 - 25 May 2000, XP002176271 Pennsylvania, USA

Oral disclosure of essential cis-acting elements essential for viral replication within ORF7 of porcine arterivirus.

D3: DATABASE GENBANK [Online] retrieved from NCBI Database accession no. NC\_001961; AF066183; AF325691; AF176348; XP002176273

Discloses several arterivirus genomes with variable ORF7 sequence as such anticipating subject-matter of most of the product-claims. [AC-number genome: (AC-number ORF7) NC\_001961: (NP\_047413.1); AF066183: (AAD27658.1); AF325691: (AAK06820); AF176348: (AAG13733.1); AF331831: (AAG49626.1); NC\_002534: (NP\_065677.1); U87392: (AAD12131.1); NC\_002533: (NP\_065668.1); M96262: (AAA46280.1); AF184212: (AAF65940); NC\_001639: (NP\_042579); AF159149: (AAG02140.1); AF046869: (AAC64690.1); U15146: (AAA85670.1)]

D4: WO 00 53787 A (NIEUWSTADT ANTONIE PAUL VAN ;LANGEVELD JAN (NL); MEULENBERG JANNEK) 14 September 2000 (2000-09-14)

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/NL02/00314

Discloses modifications and deletions within ORF-7 of PRRSV.

D5: US-A-6 110 467 (PAUL PREM S ET AL) 29 August 2000 (2000-08-29)

Discloses Iowa strain of PRRSV with modified ORF-7 (see inter alia Table III) and its utility as vaccine.

D6: WO 96 06619 A (LUM MELISSA A ;PAUL PREM S (US); HALBUR PATRICK (US); MENG XIANG J) 7 March 1996 (1996-03-07)

Discloses PRRSV strain VR 2385 and its utility as vaccine. VR2385 and Lelystad differ in ORF-7 see e.g. Figure 10.

D7: US-A-5 998 601 (ELAM MARGARET R ET AL) 7 December 1999 (1999-12-07)

Discloses ORF-7 of VR2332 and its differences to LV virus. (see e.g. Fig. 3)

D8: MEULENBERG ET AL: 'Infectious transcripts from cloned genome-length cDNA of Porcine Reproductive and Respiratory Syndrome Virus' JOURNAL OF VIROLOGY, US, THE AMERICAN SOCIETY FOR MICROBIOLOGY, vol. 72, no. 1, January 1998 (1998-01), pages 380-387, XP002112766 ISSN: 0022-538X

Discloses infectious transcripts from cloned LV virus.

D9: BRAMEL-VERHEIJE M H GROOT ET AL: 'Expression of a foreign epitope by porcine reproductive and respiratory syndrome virus.' VIROLOGY, vol. 278, no. 2, 20 December 2000 (2000-12-20), pages 380-389, XP002176272 ISSN: 0042-6822

Discloses utility of LV virus as viral vector. Transgenes introduced into ORF-7.

**Re Item V**

**Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

The claims are directed generally to arterivirus replicons characterized by deletions, e.g. missing sequences. Generally such definitions, without specification of a particular sequence sought to be protected or without specification of a particular reference sequence, are arbitrary and as such technically meaningless to the skilled person. Even if the exemplified LV-wt sequence is taken as a reference sequence all claims lack novelty in view of the above cited prior art (see D1-D7).

The patentability of the worked examples will not only be dependent on the exact content of the disclosure of D2, which is to be established during upcoming proceedings, but also on the establishment of a particular technical effect, associated with the particular replicons. This is in particular necessary, since all structural proteins were found to be dispensable for replication (see D1), as such in order to be patentable, particular selections need to be justified by a particular unexpected technical effect.

ONTVANGEN

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From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

01 SEP 2003

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To:

Prins, A.W.  
C/O VEREENIGDE  
NIEUWE PARKLAAN 97NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT

(PCT Rule 71.1)

Kopie  
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THE HAGUE

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28 AUG 2003

Beantwoord

Bericht gezonden

Vind.

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Date of mailing  
(day/month/year)

26.08.2003

Applicant's or agent's file reference

P55434PC00

## IMPORTANT NOTIFICATION

International application No.

PCT/NL02/00314

International filing date (day/month/year)

16/05/2002

Priority date (day/month/year)

21/05/2001

Applicant

ID-LELYSTAD, INSTITUUT VOOR DIERHOUDERIJ..et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

## 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

For the purpose of deciding whether the claimed invention is patentable or not, the elected Offices may apply criteria additional to or different from the criteria on which the international preliminary examination report is based (see Articles 27(5), 33(5)). Additional criteria may include e.g. exemptions from patentability and the requirements of enabling disclosure and of clarity and support of claims.

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